

REMARKS

Claims 19-32, 34 and 36-50 are all the claims pending in the application. Support for new claims 46-50 can be found, for example, on page 8, lines 23-46 of the present specification.

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 to demonstrate the difference between the present invention and USP 4,613, 500 (Suzuki), and to show that the present invention provides unexpectedly superior results.

The following method for preparing a composition comprising insulin as a drug, polyacrylic acid as a water- absorbing and water-soluble base material and crystalline cellulose as a water-absorbing and water-insoluble base material is disclosed in Suzuki. See col. 7, lines 28-45.

Firstly, polyacrylic acid was dissolved in an aqueous solution of insulin. Secondly, the solution was then freeze-dried to give a powdery composition. Then, the obtained powdery composition and microcrystalline cellulose were put in a mortar and mixed thoroughly to obtain a powdery composition.

Since the drug and water-absorbing and water-soluble base material are mixed together prior to the addition of the water-absorbing and water-insoluble base material, the drug is dispersed more on or in the water-absorbing and water-soluble base material.

In contrast, in the present invention, the drug is dispersed more on or in the water-absorbing and water-insoluble base material.

Therefore, Suzuki does not disclose, teach or suggest the present invention.

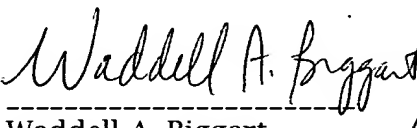
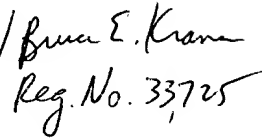
PRELIMINARY AMENDMENT
U.S. Appln. No.: 09/125,814

In addition, the present invention attains high amount of drug absorption and high maximum plasma concentration (Cmax). However, when a water-absorbing and water-soluble base material was added to the composition of Suzuki containing only a water-absorbing and water-insoluble base material, the resulting composition did not attain a higher Cmax than the composition without the water-absorbing and water-soluble base material.

Accordingly, the present invention provides unexpectedly superior results.

Entry and consideration of this Amendment is respectfully requested.

Respectfully submitted,

Waddell A. Biggart
Registration No. 24,861

SUGHRUE, MION, ZINN,
MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, D.C. 20037-3213
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

Date: March 14, 2001

PRELIMINARY AMENDMENT
U.S. Appln. No.: 09/125,814

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 46-50 are added as new claims.